## REMARKS

The Restriction Requirement requires that Applicants elect one of the following four (4) allegedly distinct inventions:

I. Claims 1-3, drawn to producing SIDR to a bacterial agent;

II. Claims 4-8, drawn to transplantation using SIDR;

III. Claim 9, drawn to a method of treating Crohn's disease; and

IV. Claim 10, drawn to a method of treating diabetes.

Applicants hereby provisionally elect Group I, which covers claims 1-3, drawn to producing SIDR to a bacterial agent, **with traverse**, and respectfully request reconsideration of the restriction requirement in view of the following remarks.

The Office Action states that "[t]he inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT rule 13.1." Office Action, p. 2. The Office Action further states

> [t]he inventions lack the same or corresponding special technical features because the inventions are obvious in view of the prior art cited in the search report supplied with the instant application (see document 371P(10/28/95) [*sic*]. In addition, Wilson et al. (US Patent 5,872,154) ["the '154 patent"] teaches the administration of recombinant adenovirus containing vector(a [*sic*] viral infectious agent) and a selected immune modulator wherein the administered agents inhibit the formation of neutralizing antibodies and/or reduce CTL against said virally infected cells. Thus, said reagents can be used to induce "selective immune down regulation" (as per the definition of said term in the specification) against a pathogen. It would have been obvious that said method could have also been used to inhibit the formation of neutralizing antibodies and/or reduce CTL against other pathogenic organisms such as bacteria, etc.

Office Action, p. 2.

However, the M.P.E.P. states:

> Unity of Invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that

> define a contribution which each of the inventions considered as a whole, makes over the prior art. . . .
>
> If the common matter of the independent claims is well known and the remaining subject matter of each claim differs from that of the others without there being any unifying novel inventive concept common to all, then clearly there is a lack of unity of invention. If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then there is unity of invention and an objection of lack of unity does not arise. . . .
>
> *[I]t is clear that the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority.*

M.P.E.P. § 1850 at 1800-95 to 1800-96 (8th ed., 2nd rev.) (emphasis added).

The International Search Report ("ISR") for PCT/US98/03606, on which the Application is based and to which the Examiner refers, searched all claims (*i.e.*, claims 1-10) and did *not* find that unity of invention was lacking. *See* Form PCT/ISA/210 (first sheet), dated June 23, 1998. Therefore, Applicants traverse the restriction requirement with regard to the alleged obviousness in view of the prior art cited in the ISR on the grounds that International Searching Authority did not find that unity of invention was lacking.

The Examiner states in the Office Action that the '154 patent teaches the administration of a recombinant adenovirus containing vector and a selected immune modulator. *See* Office Action, p. 2. However, all claims of the instant invention are nonobvious over the '154 patent because the '154 patent, alone or in combination with any other reference, neither teaches nor suggests all of the claim limitations of the present invention. The '154 patent states that the immune modulator is based on the immunoglobulin subtype of any neutralizing antibody produced in response to the adenovirus vector. Col. 3, ll. 18-22. Moreover, the '154 patent states that the immune modulators inhibit the CD4+T cell function, thereby inhibiting the formation of neutralizing antibodies, or blocks B cell activation by T helper cells, thereby reducing CTL elimination of the viral vectors. *See* col. 3, ll. 46-56. Thus, the '154 patent contemplates the use of cytokines, antibodies or other agents that nonspecifically inhibit immune function, *i.e.*, cyclosporin A or cyclophosphamide, as immune modulators. *See, e.g.*, col. 3, l. 57 to col. 4, l. 67.

By contrast, the claimed invention requires selective immune down regulation. The '154 patent's treatment modality using general immunosuppressives is *not* selective immune down

regulation. The Office Action states that the '154 patent "teaches the administration of recombinant adenovirus containing vector . . . and a *selected* immune modulator . . . . Thus, said reagents can be used to induce '*selective* immune down regulation.'" Office Action, p. 2 (emphasis added). Applicants respectfully point out that the terms "selected," as used in the Office Action to refer to immune modulators disclosed in the '154 patent, and "selective," as recited in Applicants' claims, do not refer to the same aspect of modalities and immunological states. The term "selected" refers to a user choosing a particular immune modulator. In contrast, the term "selective" refers to the action of the immune modulator. While the immunosuppressives disclosed in the '154 patent may be "selected" as immune modulators by a user, such immunosuppressives are not "selective" since they are general immune suppressives.

Each claim in all of Groups I-IV requires selective immune down regulation. Selective immune down regulation is established in a subject by, for example, introducing to said subject an immunogenic component such as an antigen. The mechanism for the selective immune down regulation of the claimed invention is based on the immunogenic component itself. In contrast, the '154 patent states that an immune modulator is used that inhibits or blocks the binding of the antibody produced in response to an antigen. Consequently, selective immune down regulation is completely absent from the teachings of the '154 patent. Therefore, the '154 patent does not teach or suggest all of the limitations of the claimed invention. Accordingly, the '154 patent does not render the claimed invention obvious.

Thus, Applicants traverse the restriction requirement because there is a technical relationship among all of Groups I-IV involving special technical features that provide a unifying inventive concept that is novel and nonobvious, and, in particular, novel and nonobvious over the '154 patent and the other references cited in the ISR. As a special technical relationship exists among all of the claims, Applicants submit that unity of invention exists between all of the currently restricted claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the Restriction Requirement under 35 U.S.C. §§ 121 and 372.

## CONCLUSION

Applicants maintain that the restriction requirement is improper and that all pending claims, *i.e.*, claims 1-10, should be examined for patentability. If the Examiner believes that the prosecution might be advanced by discussing the application with Applicants' representatives, in person or over the telephone, we would welcome the opportunity to do so.

Respectfully submitted,

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